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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,640	02/11/2000	HIROYUKI ODAKA	2477US0P	2112

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EXAMINER
JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 03/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/485,640	ODAKA ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 13-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-10 and 13-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on December 18, 2002 in Paper No. 7 wherein claims 11-12 have been cancelled, and claims 1-10 have been amended, and claims 13-27 are newly submitted. Currently, claims 1-10 and 13-27 are pending in this application.

Applicant's amendment filed on December 18, 2002 in Paper No. 7 with respect to the rejection of claims 1-12 made under 35 U.S.C. 112 second paragraph for the use of the indefinite expressions, i.e., "TNF-α" in claims 1, 11 and 12 of record stated in the Office Action dated June 19, 2001 have been fully considered and found persuasive to remove the rejection since claim 1 has been amended using the expression "Tumor Necrosis Factor -α" as "TNF-α" and claims 11-12 have been cancelled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Stevenson et al. (of record stated in the Office Action dated June 19, 2001).

Stevenson et al. discloses that three particular active agents, ciglitazone, troglitazone, and pioglitazone (5-[4-[2-(5-ethyl-2-pyridyl)ethoxy]benzyl]-2,4-thiazolidinedion), within the instant claim, are anti-diabetic agents known useful in a composition and in a method of reducing of the elevated Tumor Necrosis Factor -α (TNF-α) mRNA levels in mammal (e.g. mice) and also useful in the treatment of non-insulin-dependent diabetes mellitus in mammal (diabetic patient). See Introduction on page 175, and Figure 1 on page 176, and pages 185 to 1st paragraph of page 186, the last paragraph of page 186 to 187. Stevenson's disclosure inherently treats Tumor Necrosis Factor-α mediated inflammatory disease in a mammal such as diabetic complications (the inflammatory disease), as claimed herein since Stevenson's method steps are same as the instant method steps. See *Ex parte Novitski*, 26 USPQ 2d 1389. Moreover, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency as it related to the claimed invention herein. Thus, Stevenson et al. anticipates the claimed invention.

Applicant's remarks filed on December 18, 2001 with respect to the rejection of claims 1-9, and 11 made under 35 U.S.C. 102(b) as being anticipated by Stevenson et al. of record stated in the Office Action dated June 19, 2001 have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art as discussed in the set forth 102(b) rejection above. Applicant arguments that Stevenson et al. is limited to the described physiology of fat cells and there is therefore

no teaching and no suggestion of all of limitations of the method of the claimed invention are not found persuasive. Stevenson clearly discloses that thiazolidinedione derivatives herein are reductions in TNF-α. More importantly, Stevenson's method steps are same as the instant method steps. Therefore, Stevenson et al. anticipates the claimed invention.

Claims 1-9 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Szalkowski et al. (of record stated in the Office Action dated June 19, 2001).

Szalkowski et al. discloses that thiazolidinedione derivatives such as three particular active agents, ciglitazone, pioglitazone, and CS-045 (troglitazone), within the instant claim, are anti-diabetic agents known useful in a composition and in blocking the inhibitory effect of TNF-α on differentiation, insulin-stimulated glucose uptake in mammals (*in vivo*), and therefore useful in a method of the treatment of non-insulin-dependent diabetes mellitus in animals (*in vivo*). See abstract and page 1474, Figure 1 on page 1476 and page the left column on page 1480. See Introduction on page 175, and Figure 1 on page 176, and pages 185 to 1st paragraph of page 186, the last paragraph of page 186 to 187. Szalkowski's disclosure inherently treats Tumor Necrosis Factor-α mediated inflammatory disease in a mammal such as diabetic complications (the inflammatory disease), as claimed herein since Szalkowski's method steps are same as the instant method steps. See *Ex parte Novitski*, 26 USPQ 2d 1389. Moreover, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252,

1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency as it related to the claimed invention herein. Thus, Szalkowski et al. anticipates the claimed invention.

Applicant's remarks filed on December 18, 2001 with respect to the rejection of claims 1-9, and 11 made under 35 U.S.C. 102(b) as being anticipated by Szalkowski et al. of record stated in the Office Action dated June 19, 2001 have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art as discussed in the set forth 102(b) rejection above. Applicant asserts that Szalkowski et al. is limited to the specific description of diabetes and insulin resistance and there is therefore no teaching of any therapeuticc treatment. Hever, Szalkowski et al. clearly discloses that thiazolidinedione derivatives herein are anti-diabetic agents and are known to be useful in treating diabetes and insulin resistance. It is noted that Szalkowski's method steps are same as the instant method steps. Therefore, Szalkowski et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10, 13, and 14-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevenson et al. and Szalkowski et al. (of record stated in the Office Action dated June 19, 2001) in view of Applicant's admission regarding the prior art in the instant specification (page 18 lines 8-14).

Stevenson et al. discloses that three particular active agents, ciglitazone, troglitazone, and pioglitazone (thiazolidinedione derivatives), within the instant claim, are anti-diabetic agents known useful in a composition and in a method of reducing of the elevated Tumor Necrosis Factor -α (TNF-α) mRNA levels in mammal (e.g. mice) and also useful in the treatment of non-insulin-dependent diabetes mellitus in mammal (diabetic patient). See Introduction on page 175, and Figure 1 on page 176, and pages 185 to 1st paragraph of page 186, the last paragraph of page 186 to 187. Stevenson et al. also discloses the dose of troglitazone to be administered to human diabetic patient (NIDDM) is 4-7 mg/kg per day, within the instant claim (page 187 2nd paragraph).

Szalkowski et al. discloses that thiazolidinedione derivatives such as three particular active agents, ciglitazone, pioglitazone, and CS-045 (troglitazone), within the instant claim, are anti-diabetic agents known useful in a composition and in blocking the inhibitory effect of TNF-α on differentiation, insulin-stimulated glucose uptake in mammals (*in vivo*), and therefore useful in a method of the treatment of non-insulin-dependent diabetes mellitus in animals (*in vivo*). See abstract and page 1474, Figure 1 on page 1476 and page the left column on page 1480. See Introduction on page 175, and Figure 1 on page 176, and pages 185 to 1st paragraph of page 186, the last paragraph of page 186 to 187.

The prior art does not expressly disclose that thiazolidinedione derivatives herein which may be the particular compounds, (R)-(+)-5-[3-[4-[2-(2-furyl)-5-methyl-4-oxazolylmethoxy]-3-methoxyphenyl]propyl]-2,4-oxazolidinedion and 5-[[4-[2-(methyl-2-pyridylamino)ethoxy]phenyl]methyl]-2,4-thiazolidinedion, are useful in a method for treating a Tumor Necrosis Factor-α mediated inflammatory disease in a mammal such as diseases herein.

Applicant's admission regarding the prior art teaches that the instant diseases such as diabetic complications, rheumatoid arthritis, osteoarthiritis, and other diseases herein are known Tumor Necrosis Factor-α mediated inflammatory diseases. See page 18 lines 8-14.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ thiazolidinedione derivatives herein which may be the particular compounds, (R)-(+)-5-[3-[4-[2-(2-furyl)-5-methyl-4-oxazolylmethoxy]-3-methoxyphenyl]propyl]-2,4-oxazolidinedion and 5-[[4-[2-(methyl-2-pyridylamino)ethoxy]phenyl]methyl]-2,4-thiazolidinedion, are useful in a method for treating a Tumor Necrosis Factor-α mediated inflammatory disease in a mammal such as diseases herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ thiazolidinedione derivatives which may be the particular compounds, (R)-(+)-5-[3-[4-[2-(2-furyl)-5-methyl-4-oxazolylmethoxy]-3-methoxyphenyl]propyl]-2,4-oxazolidinedion and 5-[[4-[2-(methyl-2-pyridylamino)ethoxy]phenyl]methyl]-2,4-thiazolidinedion, are useful in a method for

treating a Tumor Necrosis Factor-α mediated inflammatory disease in a mammal such as diseases herein since thiazolidinedione derivatives of the formula in the instant claim 1 including the particular compounds herein are known to be useful in a composition and in a method of reducing of the elevated Tumor Necrosis Factor-α mRNA levels in mammal, and are therefore useful broadly in the treatment of a Tumor Necrosis Factor-α mediated inflammatory disease in a mammal such as non-insulin-dependent diabetes mellitus based on the prior art. Moreover, according to Applicant's admission regarding the prior art, the instant diseases such as diabetic complications, rheumatoid arthritis, osteoarthiritis, and other diseases herein are known Tumor Necrosis Factor-α mediated inflammatory diseases. Therefore, one of ordinary skill in the art would have reasonably expected that thiazolidinedione derivatives would exhibit their known therapeutic effect in the particular disease of Tumor Necrosis Factor-α mediated inflammatory diseases herein, absent evidence to the contrary.

Applicant's remarks filed on December 18, 2001 with respect to the rejection of claims 10 and 12 made under 35 U.S.C. 103(a) as being unpatentable over Stevenson et al. and Szalkowski et al. of record stated in the Office Action dated June 19, 2001 have been fully considered but they are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as discussed in the set forth 103(a) rejection above. Applicant argues that the combination of art does not teach or suggest the claim invention and the Examiner's rejection is made using improper hindsight. Applicant's arguments are not found convincing since both Stevenson et al. and Szalkowski et al. teach that same thiazolidinedione derivatives are useful in the

same treatment of diabetes and insulin resistance. Stevenson et al. also discloses that these active compounds are known to be useful in reducing of the elevated Tumor Necrosis Factor -α (TNF-α) mRNA levels in mammal. Hence, Stevenson et al. has provided the motivation to employ the active compounds herein to treat a TNF-α mediated inflammatory disease in a mammal. Therefore, motivation to combine the teachings of the prior art to make the present invention is seen and no improper hindsight is seen. The claimed invention is clearly obvious in view of the prior art.

Claims 1-10 and 13-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikeda et al. (6,133,293 and 6,172,089) in view of Stevenson et al. (of record stated in the Office Action dated June 19, 2001) and Applicant's admission regarding the prior art in the instant specification (page 18 lines 8-14).

Ikeda et al. discloses that active compounds herein in effective amounts, within the instant claim, are useful in a pharmaceutical composition and a method for prophylaxis or the treatment of diabetes in animals. See '293 col.2 – col.10, Working Examples 1-3, and claims 1-13; and '089 col.2 – col.10, Working Examples 1-3, and claims 1-7.

Ikeda et al. does not expressly disclose that active compounds herein are useful in a method for treating a TNF-α mediated inflammatory disease in a mammal such as diabetic complications, rheumatoid arthritis, osteoarthiritis, and other diseases herein.

Stevenson et al. teaches that active compounds, within the instant claim, are anti-diabetic agents known useful in a composition and a method of reducing of the

elevated TNF-α mRNA levels in a mammal and also useful in the treatment of non-insulin-dependent diabetes mellitus in mammal. See Introduction on page 175 and Figure 1 on page 176, and pages 185 to 1st paragraph of page 186.

Applicant's admission regarding the prior art teaches that the instant diseases such as diabetic complications, rheumatoid arthritis, osteoarthiritis, and other diseases herein are known Tumor Necrosis Factor-α mediated inflammatory diseases. See page 18 lines 8-14.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ active compounds herein are useful in a method for treating a TNF-α mediated inflammatory disease in a mammal such as diabetic complications, rheumatoid arthritis, osteoarthiritis, and other diseases herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ active compounds herein are useful in a method treating a TNF-α mediated inflammatory disease in a mammal such as diabetic complications, rheumatoid arthritis, osteoarthiritis, and other diseases herein since active compounds herein are known to be useful in a pharmaceutical composition and a method of treating diabetes in a mammal. Moreover, active agents herein are known to be useful in a method of treating insulin-resistant diabetes mellitus by reducing the elevated TNF-α mRNA levels in mammal based on the teaching of Stevenson et al. Further, the instant diseases such as diabetic complications, rheumatoid arthritis, osteoarthiritis, and other diseases herein are known Tumor Necrosis Factor-α mediated inflammatory diseases based on Stevenson et al. and Applicant's admission herein.

Therefore, one of ordinary skill in the art would have reasonably expected that these active compounds would have a beneficial therapeutic effect on Tumor Necrosis Factor-α mediated inflammatory diseases herein in a mammal, absent evidence to the contrary.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's remarks filed on December 18, 2001 with respect to the rejection of claims 1-12 made under 35 U.S.C. 103(a) as being unpatentable over Ikeda et al. (6,133,293 and 6,172,089) in view of Stevenson et al. of record stated in the Office Action dated June 19, 2001 have been fully considered but they are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as discussed in the set forth 103(a) rejection above. Applicant argues that the combination of art does not teach or suggest the claim method of the present invention with a reasonable success and the Examiner's rejection is made using improper hindsight. Applicant's arguments are not found persuasive since both Ikeda et al. and Stevenson et al. teach that same thiazolidinedione derivatives are useful in the same treatment of diabetes and insulin resistance. Stevenson et al. also discloses that these active compounds are known to be useful in reducing of the elevated Tumor Necrosis Factor - α (TNF-α) mRNA levels in mammal. Hence, Stevenson et al. has provided the motivation to employ the active compounds herein to treat a TNF-α mediated inflammatory disease in a mammal. Therefore, motivation to combine the teachings of

the prior art to make the present invention is clearly seen and no improper hindsight is seen. The claimed invention is clearly obvious in view of the prior art.

Applicant's data shown in the specification at pages 23-28 herein have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention over the prior art but are not deemed persuasive for the reasons below. The results on test on the employment of several instant compounds in fatty obese and diabetic rats show expected therapeutic effects as taught and suggested by the cited prior art herein. Therefore, the results herein are clearly expected and not unexpected based on the cited prior art. Expected beneficial results are evidence of obviousness. See MPEP § 716.02(c). Moreover, The results herein merely demonstrate that the four particular compounds, for example, Compound No. 1 and 8 (see Table 1-4), within the instant claims, are useful in particular TNF-α mediated inflammatory diseases, diabetes and obese. Thus, the evidence in the examples is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the active compounds and TNF-α mediated inflammatory diseases in the instant claims. See MPEP § 716.02(d). Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art. Further, Examples herein provide no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 and 13-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,965,584 in view of Stevenson et al. essentially for reasons of record stated in the Office Action dated June 19, 2001.

Applicant's remarks filed on December 18, 2001 with respect to this rejection have been fully considered but they are not deemed persuasive as to remove the Double Patenting rejection. Applicant argues that the combination of art does not teach or suggest the claim method of the present invention. Applicant's arguments is not found persuasive since both Ikeda et al. and Stevenson et al. teach that same thiazolidinedione derivatives are useful in the same treatment of diabetes and insulin

resistance. Stevenson et al. also discloses that these active compounds are known to be useful in reducing of the elevated Tumor Necrosis Factor -α (TNF-α) mRNA levels in mammal. Hence, Stevenson et al. has provided the motivation to employ the active compounds herein to treat a TNF-α mediated inflammatory disease in a mammal. Therefore, for the above stated reasons, said claims are properly rejected under the judicially created doctrine of obviousness-type double patenting. Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
February 25, 2002

MINNA MOEZIE, J.D.
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